

FCL 26

## 5 510(k) Summary

**Submitter's information:** Radi Medical Systems AB  
Palmbladsgatan 10  
SE-754 50 Uppsala, Sweden  
Phone:(+46) 18161000

**Contact Person:** Helene Ekstrand

**Date Prepared:** January 23<sup>rd</sup>, 2008

**Proprietary Name:** FemoStop® Femoral Compression System

**Regulation Name:** Vascular clamp

**Product code:** DXC

**Predicate Devices:** K024107 FemoStop® HD Femoral Compression System  
K062033 BP101 Digital Blood Pressure Monitor

**Description of the Device:** This combination of FemoStop® Femoral Compression System consists of an arch with a sterile pneumatic pressure dome, an integrated pump with a digital manometer, a belt and a hemostatic dressing and is called FemoStop® Gold Femoral Compression System. The pressure dome is placed over the vessel puncture site in the groin. The belt is placed around the patient. The dome applies mechanical pressure over the vessel puncture site to induce hemostasis. The pressure of the dome is controlled by the integrated pump and the manometer. The arch and belt provide counter pressure for the dome. The sterile hemostatic dressing is placed on the skin incision site as a bacterial barrier and for topical control of bleeding.

**Indication for Use of the Device:** FemoStop® Femoral Compression System is indicated for use in the compression of the femoral artery or vein after vessel cannulation, and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.

**Technical Characteristics:** The technical characteristics of the actual FemoStop® are identical to those of the predicate FemoStop® Femoral Compression System except for the integration of a single-use digital pump.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 26 2008

Radi Medical Systems AB  
c/o Ms. Helene Ekstrand  
Regulatory Affairs Officer  
Palmladsgatan 10  
SE-75450 Uppsala  
Sweden

Re: K080206  
Femostop Femoral Compression System  
Regulation Number: 21 CFR 870.4450  
Regulation Name: Vascular Clamp  
Regulatory Class: Class II (two)  
Product Code: DXC  
Dated: January 23, 2008  
Received: January 28, 2008

Dear Ms. Ekstrand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

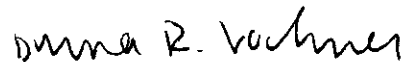
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#### 4 Indications for Use

510(k) Number: K080206

Device Name: FemoStop® Femoral Compression System

Indications for Use: FemoStop® Femoral Compression System is indicated for use in the compression for the femoral artery or vein after vessel cannulation, and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm

Prescription Use X

AND/OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Kichner  
(Division Sign-Off)  
Division of Cardiovascular Devices

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